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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,617	03/15/2001	Paul O. Sheppard	98-29D1	6610
7590	04/02/2004		EXAMINER KERR, KATHLEEN M	
Robyn Adams Patent Department ZymoGenetics, Inc. 1201 Eastlake Avenue East Seattle, WA 98102			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 04/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/809,617	<b>Applicant(s)</b> SHEPPARD ET AL.	
	<b>Examiner</b> Kathleen M Kerr	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1/20/04.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11, 12, 18-23, 36, 38, 40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 12, 18, 20-23, 38, 40 and 41 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/3/04</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1652

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-final rejection (mailed on June 2, 2003), Applicants filed a response and amendment received on December 3, 2003 (incomplete reply) and January 20, 2004. Said amendment cancelled Claims 8, 9, 13, 15, 29-35, 37, and 39 and amended Claims 20, 38, and 41. Thus, Claims 11, 12, 18-23, 36, 38, and 40-41 are pending in the instant Office action and will be examined herein.

### ***Priority***

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/092,371 filed on July 10, 1998 and U.S. non-Provisional Application No. 09/351,414 filed on July 9, 1999 (the divisional parent application).

### ***Information Disclosure Statement***

3. The information disclosure statement filed on December 3, 2003 fails to comply with 37 C.F.R. § 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The following references were not considered for the reasons described below:

- a) Foreign Documents A1 and A2: These references have previously been cited by the Examiner on June 2, 2003.
- b) Other Document A4: This reference has previously been cited by the Examiner on June 2, 2003.
- c) Other Document A5 (Hochuli *et al*): No copy of this reference was provided; said reference is not of record in the parent application.
- d) Other Documents A53-A55: These references have previously been cited by Applicants on February 28, 2002 and noted by the Examiner on June 2, 2003.

Art Unit: 1652

All other documents in said Information Disclosure statement were considered as noted by the Examiner initials in the copy attached hereto. Applicants must file a copy of the Hochuli *et al.* reference for its consideration.

***Compliance with the Sequence Rules***

4. In response to the previous Office action, Applicants deleted a 6-mer polypeptide is disclosed without benefit of a SEQ ID NO from page 90. This deletion does not compromise the understanding of the example. The instant application now fully complies with the sequence rules.

***Withdrawn - Objections to the Specification***

5. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicants' amendment to the title.

6. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicants' amendment to the Abstract.

7. Previous objection to the specification for inappropriate notation of an internet address is withdrawn by virtue of Applicants' deletion of the internet addresses from the specification.

These deletions do not compromise the understanding the specification.

Art Unit: 1652

***Withdrawn - Claim Objections***

8. Previous objection to Claims 30 and 31 under 37 C.F.R. § 1.75 as being a substantial duplicate of claims 29 and 9, respectively, is withdrawn by virtue of Applicant's cancellation of Claims 30 and 31.

9. Previous objection to Claims 37 and 39 for a typographical error is withdrawn by virtue of Applicants' cancellation of said claims.

10. Previous objection to Claim 38 for depending from a rejected claim is withdrawn by virtue of Applicants' amendment to Claim 38 rendering said claim independent.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

11. Previous rejection of Claim 8 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn by virtue of Applicants' cancellation of said claim.

12. Previous rejection of Claim 15 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn by virtue of Applicants' cancellation of said claim.

13. Previous rejection of Claims 20-23 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn by virtue of Applicants' amendment to said claims.

14. Previous rejection of Claims 30 and 31 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn by virtue of Applicants' cancellation of said claims.

Art Unit: 1652

15. Previous rejection of Claims 32 and 33 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn by virtue of Applicants' cancellation of said claims.
16. Previous rejection of Claim 41 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn by virtue of Applicants' amendment to said claim.
17. Previous rejection of Claims 8, 15, 32, 34, 35, 37, and 39 under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicants' cancellation of said claims.
18. Previous rejection of Claims 8, 15, and 29 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation of said claims.
19. Previous rejection of Claims 9 and 30-33 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation of said claims.
20. Previous rejection of Claim 13 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation of said claim.
21. Previous rejection of Claim 13 under 35 U.S.C. § 112, first paragraph, enablement, is withdrawn by virtue of Applicants' cancellation of said claim.

***Withdrawn - Claim Rejections - 35 U.S.C. § 101***

22. Previous rejection of Claim 13 under 35 U.S.C. § 101 because the claimed invention is not supported by either an asserted utility or a well-established utility is withdrawn by virtue of Applicants' cancellation of said claim.

***Withdrawn- Claim Rejections - 35 U.S.C. § 102***

23. Previous rejection of Claims 8, 15, 32, 34, 35, 37, and 39 under 35 U.S.C. § 102(b) as being anticipated by Sagane *et al.* is withdrawn by virtue of Applicants' cancellation of said claims.
24. Previous rejection of Claims 9, 29-31, 33 under 35 U.S.C. § 102(a) as being anticipated by Sagane *et al.* is withdrawn by virtue of Applicants' cancellation of said claims.
25. Previous rejection of Claims 8, 15, 32, 34, and 35 under 35 U.S.C. § 102(b) as being anticipated by Sagane is withdrawn by virtue of Applicants' cancellation of said claims.
26. Previous rejection of Claims 8, 32, 34 under 35 U.S.C. § 102(e) as being anticipated by Fanslow *et al.* is withdrawn by virtue of Applicants' cancellation of said claims.

**NEW ISSUES**

***Claim Objections***

27. Claim 19 is objected to for depending from a rejected claim.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1652

28. Claim 38 is rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended Claim 38 is identical to previous Claim 37, which was rejected for new matter in the previous Office action as follows: “which has at least 90% identity to the amino acid sequence as shown in SEQ ID NO:2 from residue 164 to residue 696” is considered new matter. The only mention of 90% identical is related to polypeptides, specifically the entirety of SEQ ID NO:2 (see page 26). No arguments were made by Applicants concerning the new matter rejection of Claim 37.

As previously noted for Claim 37, present Claim 38 is not supported in the instant specification, thus, an earliest date of March 15, 2001 is all that can be afforded to Claim 38. All other pending claims are afforded the earliest effective filing date of July 10, 1998 from the provisional application.

29. Claims 11, 12, 18, 20-23, and 36 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In each of the above claims, open claim language reads on polynucleotides encoding full-length proteins; however, only a portion of the disclosed full-length protein taught in the specification is a claim limitation.



The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, a polynucleotide encoding a multi-domain protein is described in the form of SEQ ID NO:1, which encodes SEQ ID NO:2, a 696 amino acid protein. The domains of this polypeptide are 1-163 (propeptide domain), 164-382 (protease domain), 383-464 (disintegrin domain which binds integrin), and 465-696 (cysteine-rich domain). In each of the instant claims, a limited portion of the full-length protein is required with no requisite function of the full-length protein (as afforded by the open claim language) encoded by the claimed polynucleotide. Such a limited portion cannot, itself, support the function since said function is not necessarily inherent if the domain were to be found in a wholly distinct protein (see *IDS-Sagane et al.* 1998, page 93). By virtue of the open claim language, **any** additional structure can be added to the limited portion of structure required by the claims to produce the

Art Unit: 1652

claimed, functional polynucleotide. Without any correlation of how the structure of the single species disclosed performs the claimed function, one of skill in the art would be unable to recognize the structure of the other members of the claimed genus by virtue of the instant disclosure. Therefore, claims are not adequately described by the specification as originally filed.

The Examiner suggests insertion of functional language (protease or disintegrin or both functionality) to appropriately link the required fragment function to be identical to any full-length polynucleotide within the scope of the claims.

30. Claim 38 is rejected under 35 U.S.C. 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 38 is drawn to polynucleotides encoding polypeptides having at least 90% with a fragment of SEQ ID NO: 2.

The Court of Appeals for the Federal Circuit has recently held as described above.

The instant specification discloses as described above.

The Examiner suggests the insertion of a functional limitation on the polynucleotides in the genus of claim 38 that related to either protease functionality or the disintegrin functionality.

31. Claims 38 and 40 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for polynucleotides that exactly encode particular domains of SEQ ID NO:2, does not reasonably provide enablement for polynucleotides that encode related polypeptides. The specification does not enable any person

Art Unit: 1652

skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To make the invention to the full extent of its scope would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The instant specification teaches SEQ ID NO:2, a multi-domain protein (zdint1) comprising at least a protease domain, a disintegrin domain, and a cysteine-rich domain. The art includes few examples of such multi-domain proteins. The art fully enables any DNA encoding SEQ ID NO:2 based on the degeneracy of the genetic code. While the instant specification

Art Unit: 1652

describes and enables means for identifying other *zdint1* genes using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotides within the scope of the claims because the ability to find a *zdint1* gene, which is structurally related to SEQ ID NO:1, is not equivalent to the ability to make a *zdint1* gene as required by the statute (i.e., “make and use”). No description in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its *zdint1*-nature is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

***Claim Rejections - 35 U.S.C. § 101***

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

32. Claim 41 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claim 41, as written, does not sufficiently distinguish over polynucleotides as they naturally exist because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206, USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g. by insertion of “isolated” or “purified” as taught by the specification. See M.P.E.P. § 2105.

Art Unit: 1652

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

33. Claim 38 is rejected under 35 U.S.C. § 102(b) as being anticipated by Sagane *et al.* (August, 1998). The instant claims are drawn to polynucleotides encoding polypeptides having at least 90% sequence identity to residues 164-696 of SEQ ID NO:2.

Sagane *et al.* teach a 3054 base pair polynucleotide that encodes MDC3. Said polynucleotide encodes residues 9-664 of SEQ ID NO:2 with two mismatches in the region between 164 and 382 (see previously attached alignments). While the C-terminus of SEQ ID NO:2 is not taught, claims drawn to polynucleotides encoding a polypeptide having at least 90% identity to SEQ ID NO:2 from 164-696 are anticipated because this region is 90% identical over its full-length, even considering the missing amino acids.

***Summary of Pending Issues***

34. The following is a summary of the issues pending in the instant application:

- a) Claim 19 is objected to for depending from a rejected claim.
- b) Claim 38 is rejected under 35 U.S.C. § 112, first paragraph, new matter.
- c) Claims 11, 12, 18, 20-23, and 36 are rejected under 35 U.S.C. § 112, first paragraph, written description.
- d) Claim 38 is rejected under 35 U.S.C. 112, first paragraph, written description.
- e) Claims 38 and 40 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
- f) Claim 41 is rejected under 35 U.S.C. § 101.
- g) Claim 38 is rejected under 35 U.S.C. § 102(b) as being anticipated by Sagane *et al.* (August, 1998).

Art Unit: 1652

***Conclusion***

35. Claim 19 is objected to. Claims 11, 12, 18, 20-23, 36, 38, and 40-41 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is **NON-FINAL** due to the new grounds of rejection presented herein that were not the result of Applicants' amendments (see item c, d, e, and f in above summary).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr  
Examiner  
Art Unit 1652

March 30, 2004